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Examining Group 1617 Patent Application

Docket No. UTR-104

Serial No. 09/634E

23,2001

Frank C. Eisenschenk, Ph.D., Patent Attorney

AU6 2 7 209

DECLARATION UNDER 37 C.F.R. § 1.131

IN THE UNITED STATES PATENT AND TRADES

Examiner

D.C. 20231 on August

Helen Nguyen

Art Unit

1615

Applicants

Michael B. Zemel, Hang Shi, Paula C. Zemel

Serial No.

09/654,357

Filed

September 1, 2000

For

Materials and Methods for the Treatment or Prevention of Obesity

Commissioner of Patents and Trademarks Washington, D.C. 20231

DECLARATION UNDER 37 C.F.R. § 1.131

Sir:

DR. MICHAEL B. ZEMEL, DR. HANG SHI, AND DR. PAULA C. ZEMEL DECLARE:

- 1. THAT we are co-inventors of the invention disclosed and claimed in U.S. Application Serial No. 09/654,357.
- 2. THAT said invention was completed in the United States prior to January 2000, as shown by the following exhibits. We conceived and reduced to practice methods for the stimulation of lipolysis in animals by increasing the amounts of dietary calcium consumed by these animals. Dietary calcium is provided in the form of calcium carbonate or powdered non-fat milk. Exhibit 1 shows that increasing dietary calcium stimulates lipolysis. The effects of a high calcium diet on adipocyte lipolysis was assayed using a glycerol release assay as described in Example 2 of the above-identified patent application.

3. That Exhibit 1 is a copy of pages taken from a laboratory record created and maintained in the normal course of laboratory operations, prior to January 2000. The completion date of the experiments and analyses recorded in these laboratory notebook pages have been redacted. We hereby attest that these redacted dates are prior to the critical date.

We hereby further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.



PHOTOMETRY/GLYCL-ni

				٠,
STD 1	1 0.1	0.000		
STD 1	1.30	0.000		
Mf AA	845	SD=	1) 000	RGD= 0.489
5119 -		1.000	3.005	K3D= U.488
SH		1.000		
		1.000		
910.A.V =	12.44	SD=	0.009	RSD= 0.072
		47 200		
3TD 3	-3.097	2,500		
MEAN=	3.078	SD=	0.026	RSD= 0.844
STD 4	3.319	5,000		0.044
3TD 4	8 315	5 000		
ME AN =	8 317	30-	n area	RSD= 0.024
	W. 2: 1		0.002	RSD = 0.024
DHI CO.	. 1 31 77	LYCEROL		
1 4 1 1 2 1 1	i mini	LYCERUL		
1.0				
1.0		mōʻzil		
# fb 1	-2.006	0.000		
: FD - 1	1.095	0.000		
M(A),=	2.000		0 00%	RSD= 0.350
1.11.2	2.986	0.050	0.001	KDD- 0.380
		0.050		
2 • • • • • • • • • • • • • • • • •	0.001		0.000	15.05
1.1	2.994	20:-	0.009	RSD= 0.30.
	8.394			
STU		0.100		
MEAN	3.405	SD-	0.016	RSD= 0.190
5770 i	-10.277	0.250 0.250		
STD 4	10.75	0.250		
MEAN =	10.76	SD =	6.014	RSD- 0.130
31D 5 3TD 5	15.30	0.500		3,150
5TD 5	15.36	0.500		
MFAN =	15.36		C	Don a cos
. CTD 6	15.44	1 000	0.700	RSD: 0.000
STD 6	15.44	1.000		
. 3(0.5	15.15	1.000		
MCAN:	10.44	SD-	0.009	RSD= 0.058
!	i. (.3	0.074		
·	4. 62	0.074		MSD= 0.000
a, Win	0.074	SD =	ម.មហ	MSD= 0.000
. (2	1.096	0.036		
, t	4.070	ย. สสิริ		
16 MEAN-	0.085	. 30=	0.000	RSD= 0.000
3	6.028	0.143		
	6.022			
Ja_MEAN=			0.00	RSD= 0.000
4		-0.0161	0.000	K30- 0.000
		-0.014L		
· _ A			0.001	Dan 0 007
*25 MEAN=	-0.015		0.001	RSD=-6.667
2	3.473	0.002		
2 C	3.479			
2. MEAN=			0.000	RSD= 0.000
6	5.089	0.092		
6	5,085	0.091	5 "	
La MEAN=	0.091	SD=	0.000	RSD= 0.000
يه و جوندويه سناڪ	4.540.	0.061		
7	4 53N	0 061	Frank Sales	1775

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MEAN= 0.091
                     SD=
                           0.000% RSD
        8 5.955 0.139
        8
           5.933 0.138
   MEAN=
           0.138
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                           0.000
                                   RSD = 0.000
        9
           5.967 0.140
        9
           5.941 0.139
(b MEAN=
           0.139
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                           0.000
                                    RSD= 0:000
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           3.946 0.028
       10
           3.929 0.028
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                                    RSD= 0.000
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       1 1
           2.259-0.065L
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                                    RSD = 0.000
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       12
           5.844 0.133
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                           0.000
                                    RSD = 0.000
           0.133
                     SD=
           6.030 0.143
       13
       13
           6.004 0.142
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           4.045 0.034
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           0.035
                           0.001
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           4.993 0.086
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                                    RSD= -0.000
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                      SD-
                           0.000
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       17
            5:020 0.063
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                                    RCD= 0.000
           0.088
                      SDa
                           0.000
       18
            5,373 0.107
       .। ध
            5,365 0.107
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                                    KSD- 0.000
           0.107
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            2.711-0.040L
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       20
            4.234 0.044
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                            0.000
            0.044
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                                    RSD= 18.89
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                      SD =
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            6.035 0.144
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                            0.000
                                    RSD= 0.000
            0.144
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            8.546 0.282
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                      SD=
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            4.842 0.078
       25
            4.841 0.078
                                    RSD= 0.000
13 a MEAN=
                            0.000
            0.078
                      SD≕
       26
            4,835 0.073
       26
            1.816 0.076
135 MEAN =
                            0.001
                                    RSD= 1.298
            0.077
                      3D=
       27
            5,661 0.123
            5,822 0,132
       27
                                    RSD = 4.724
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            0.127
                      SD=
                            0.006
          2.061-0.076L
12.028-0.077L
10.077 3.750-50.000 RSD= 0.000
       28
          7.391 1.053
 (A MEAN = 20.052 12 SD
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0.052
                              0.001
         30
              5.045 0.089
         30
              5.008 0.037
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              0.088
                        SD=
                              0.001
                                      RSD= 1.136
         31
              2.682-0.0411
         31
              2.659-0.043L
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                              0.001
                                     RSD=-2.381
         32
              5.409 0.109
         32
              5.397 0.109
              0. 109
                        SD =
                             0.000
                                     RSD = 0.000
         33
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         33
             3.110-0.018L
  1 a MEAN= -0.018
                        SD≃
                             0.000
                                     PSD= 0.000
         34
             3.300-0.002L
         34
             3.410-0.001L
  5 MEAN=
           -0.002
                       SD=
                             0.000
                                     RSD= 0.000
         35
             3.404-0.001L
         35
             3.113-0.0171.
  Lamean=
            -0.009
                       SD=
                             0.011
                                     RSD=-122.2
             2.359-0.059L
         36
         36
             2.348-0.060L
  26 MEAN=
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                                     RSD = 0.000
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                       SD=
                             0.000
                                     RSD= 0.000
        38
             3.064-0.020L
        38
             3.067-0.020L
            -0.020
                       SD=
                             0.000
                                     RSD= 0.000
        30
             2.652-0.043L
             2.640-0.044L
 午きMEAN=
            -0.044
                       3D=
                            0.000
                                    RSD= 0.000
        41)
            2.802-0.005L
        40
             2.746-0.6381.
     MEAN =
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                       3D.-
                            0.002
                                    RSD=-5.406
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             5.112 0.093
             4.785 0.075
        41
    MEAN=
            0.084
                       SD=
                            0.012
                                    RSD= 14.28
        42
            5.600 0.120
        42
            5.577 0.118
     MEAN=
            0.119
                            0.001
                                    RSD= 0.840
        43
            3.639 6.642
        43
            3.652 U.H.2
 be MEAN=
            0.012
                            0.000
                                    RSD = 0.000
        44
            5.071 0.001
        44
            5.000 0.090
 7 amean=
            0.090
                      SD=
                            0.000
                                    RSD= 0.000
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            3.980 0.030
       45
            3.985 0.031
    MEAN=
            0.030
                      SD=
                            0.000
                                    RSD = 0.000
       46
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       46
            4.212 0.043
Sa MEAN=
            0.043
                      SD=
                           0.000
                                    RSD = 0.000
            4.821 0.077
       47
       47
            4.700 0.075
85 MEAN=
           0.076
                      SD=
                           0.001
                                   RSD= 1.315
       48
            4.956 0.084
       48
            4.955 0.084
9 OLMEAN=
           0.084
                      SD=
                           0.000
                                   RSD= 0.000
       49
           4.111
                  0
                    038
      49
           4.082 0.036
   MEAN=
           0.037
                      SD=
                           0.001
                                   RSD = 2,702
       50
           4.999 0.087
       50
           5.004 0.087
O & MEAN=
           0.087
                     SD=
                           0.000
                                   RSD= 0.000
       51
           4.033 0.033
       51
           4.046 0.034
106 MEAN=
           0.033
                     SD≃
                           0.000
                                   RSD= 0.000
           4.807 0.076
       52
       52
           4.792 0.075
1 Q MEAN=
           0.075
                     SD=
                           0.000
                                   RSD = 0.000
      53
           5.049 0.089
           5.044'0.089
       53
```

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4 082 0
0:037
                           0.001
                      SD=
            4.999 0.087
       50
           5.004 0.087
  XME AN=
           0.087
                      SD=
                           0.000
                                   RSD = 0.000
            4.033 0.033
       51
       51
           4.046 0.034
JUB MEAN=
           0.033
                      SD∸
                           0.000
                                   RSD= 0.000
       52
           4.807 0.076
       52
           4.792 0.075
  a_MEAN=
           0.075
                      SD=
                           0.000
                                   RSD = 0.000
       53
           5.049 0.089
       53
           5.044 0.089
115 MEAN=
           0.089
                     SD=
                           0.000
                                   RSD = 0.000
       54
           5.669 0.124
       54
           5.674 0.124
   MEAN=
           U. 124
                     SD=
                           0.000
                                   RSD= 0.000
       55
           5.830 0.132
      55
           5.793 0.130
12-5 ME AN=
           0.131
                     SD=
                           0.001
                                   RSD= 0.763
      56
           5.551 0.117
      56
          5.523 0.115
SAMEAN-
           U.116
                     SD=
                          0.001
                                  RSD = 0.862
      57
           3.558 0.007
      57
           3.551 0.007
  hMEAN=
           0.007
                     SD=
                          0.000
                                  RSD= 0.000
      58
          6.217 0.154
      53
          6.194 0.153
4aMEAL=
          0.153
                          0.000
                                  RSD= 0.000
      59
          i.984-0.080L
      59
          1.982-0.080L
  MEAN= -0.080
                     SD=
                          0.000
                                  RSD= 0.000
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          5.393 0.108
      60
          5.395 0.108
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          0.108
                          0.000
                                  RSD= 0.000
      61
          5,425 0,110
      61
          5.424 0.110
  MEAN=
          0.110
                    SD=
                          0.000
                                  RSD= 0.000
      62
          2.896-0.029L
     62
          2.897-0.029L
  MEAN=
         -0.029
                    SD=
                          0.000
                                  RSD = 0.000
   O 63
          5.112 0.093
          5.154 0.095
   MEAN≠
          0.094
                    SD=
                          0.001
                                  RSD= 1.063
     <u> 64</u>
          5.840 0.133
     64
          5.849 0.133
  MEAN =
         0.133
                    SD=
                         0.000
                                 RSD = 0.000
         5.858 0.134
     65
         5.859 0.134
  MEAN=
         0.134
                   SD≈
                         0.000
                                 RSD= 0.000
     66
         5.02! 0.088
     66
         5.011 0.087
  MEAN =
         0.087
                   SD=
                         0.000
                                 RSD= 0.000
     67
         5.401 0.109
     67
         5.413 0.109
 MEAN=
         0.109
                   SD=
                         0.000
                                 RSD = 0.000
     68
         5.938 0.138
     68
         5.860 0.134
 MEAN=
         0.136
                   SD=
                         0.002
                                 RSD= 1.470
     69
         5.449 0.111
    a 69
         5.256 0.101
 MEAN= 0.106
                   SD=
                         0.007
                                 RSD= 6.603
   70 2.213-0.067L
70 2.209-0.067L
                        0.000
                                 RSD= 0.000
                                RSD = 0.781
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	8	0.221	0.1988						
۸ ۲ ۲۷/	100584			0.947136					
-	(100nM)								
con 1a		0.038	0.3977	0.095549					
1b		0.057	0.3636						
2a		0.058	0.4902						
2b		0.000	0.4441	0.110519					
3b		0.056	0.3771	0.148502					
4a		0.035	0.5005						
4b		0.006	0.5643		0.010633				
avg		0.000	0.0040	0.117813	0.010033			٠.	
high-Ca	а			0.117010					
5a	-	0.017	0.4475		0.037989				
5b		0.177	0.3302	0.536039	0.007,000				
6a		0.21	0.4576						
6b		0.075	0.4078	0.183914					
7a		0.174	0.3832						
7b		0.098	0.5349	0.183212					
8a		0.115	0.4088	0.281311					
8b		0.154	0.2215	0.69526					
avg				0.39896					
medium	n-dairy								
9a		0.166	0.5304	0.312971					
9b		0.107	0.4747	0.225406					
10a		0.169	0.53	0.318868					
10b		0.103	0.5327	0.193355					
11a		0.155	0.3235	0.479134					
11b		0.172	0.3931	0.437548					
12a		0.216	0.2288	0.944056					
12b		0.226	0.2761	0.818544					
avg				0.466235					
high-dai	iry	-				•		•	
13a		0.207	0.3945	0.524715					
13b		0.069	0.3999	0.172543					
14a		0.253	0.307	0.824104					
14b		0.237	0.2847	0.832455					
15a		0.196	0.2033	0.964092					
15b		0.198	0.3495	0.566524	0.054545				
16a		0.023	0.4219	0.400500	0.054515				
16b		0.18	U.4152	0.433526					
avg				0.616851					